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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,708	09/29/2003	Nicholas Kim Hayward	10441ZY	2634

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,708

Applicant(s)

HAYWARD ET AL.

Examiner

Christine J. Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-41(2) is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 and 35-41(2) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Sequence Compliance

Prior to examination of the instant application, the specification and the Sequence Listing must be corrected to clarify the amino acid and nucleic acid sequences which are contained in the instant application, and which the claims refer to. For example, in the paper copy of the Sequence Listing, SEQ ID NO:4, 8 and 10 are listed as nucleotide sequences, but they are actually polypeptide sequences. In the Brief Description of the Figures, there is no mention of the SEQ ID NO's for the sequences in the figures – the reference to the SEQ ID NO's must either be present in the Figures themselves or be found in the Brief Description of the Figures. The specification refers to SEQ ID NO:3 as a protein sequence, but it is actually a nucleotide sequence.

These are deficiencies that not only do not comply with the Sequence Rules, but will hinder the prosecution of the instant application. To avoid unnecessary rejections and objections as well as misunderstandings as to the subject matter of the claims, Applicant is invited to review the entire specification, figures and sequence listing to confirm that the sequences are referenced as SEQ ID NO's, that the sequences are correctly identified as polynucleotide or polypeptide sequences, and that the Sequence Rules are met. Applicant's cooperation in this matter will only assist in the prosecution of the instant application.

Claim numbering

Applicant should note that there are 2 claims numbered as "41". Applicant should correct this deficiency in the next response.

Improper Multiple Dependent Claims

Claims 34 is an improper multiple dependent claim, and therefore it is withdrawn from consideration and not been treated further on the merits (which is why it is not included in any of the inventive Groups below).

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a polypeptide related to SEQ ID NO:2, classified in at least class 530, subclass 350, for example.
- II. Claims 1, 11, 15, 19, 20, and 22, drawn to a polypeptide related to SEQ ID NO:4, classified in at least class 530, subclass 350, for example.
- III. Claims 1, 12, 16, 19, 20, 21 and 23, drawn to a polypeptide related to SEQ ID NO:6, classified in at least class 530, subclass 350, for example.
- IV. Claims 1, 13, 17, 19, 20 and 24, drawn to a polypeptide related to SEQ ID NO:8, classified in at least class 530, subclass 350, for example.
- V. Claims 1, 14, 18, 19, 20 and 25, drawn to a polypeptide related to SEQ ID NO:10, classified in at least class 530, subclass 350, for example.
- VI. Claims 26-28, 30-32, 35, drawn to a polynucleotide related to a polynucleotide encoding SEQ ID NO:2, classified in at least class 435, subclass 69.1, for example.

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- VII. Claims 26-28, 30-31, 35-36 drawn to a polynucleotide related to a polynucleotide encoding SEQ ID NO:4, classified in at least class 435, subclass 69.1, for example.
- VIII. Claims 26-28, 30-31, 35, drawn to a polynucleotide related to a polynucleotide encoding SEQ ID NO:6, classified in at least class 435, subclass 69.1, for example.
- IX. Claims 26-28, 30-31, 35 drawn to a polynucleotide related to a polynucleotide encoding SEQ ID NO:8, classified in at least class 435, subclass 69.1, for example.
- X. Claims 26-28, 30-31, 35, drawn to a polynucleotide related to a polynucleotide encoding SEQ ID NO:10, classified in at least class 435, subclass 69.1, for example.
- XI. Claims 26-28, 33 and 35, drawn to a polynucleotide encoding a murine VEGF, classified in at least class 435, subclass 69.1, for example.
- XII. Claims 37-38 and 40-41, drawn to a method of inducing proliferation by administration of a polypeptide of SEQ ID NO:3, classified in at least class 514, subclass 2, for example.
- XIII. Claims 37, 39, 40 and 41(second one), drawn to a method of inducing proliferation by administration of a polypeptide of SEQ ID NO:6, classified in at least class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are all directed to various VEGF proteins, which differ in amino acid sequence. While each of the different proteins of the inventive groups are all considered VEGF molecules, they each have their own unique properties, and therefore, their own modes of operation (i.e. receptor binding) and their own biological effects. Furthermore, a search of one protein would not necessarily reveal art on any of the other proteins. Therefore, the searches for each invention in Groups I-V, although

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classified alike, are not coextensive and would require a specific, unique search of the amino acid sequence of each protein claimed.

Inventions VI-XI are all directed to various polynucleotides encoding various VEGF proteins, which differ in their primary structure of nucleic acid sequence, as well as encoding proteins which differ in their primary structure of amino acid sequence. While each of the different polynucleotides of the inventive groups all encode VEGF molecules, each encoded protein has its own unique properties, and therefore, its own mode of operation (i.e. receptor binding) and biological effects. Furthermore, a search of polynucleotide and the protein encoded thereby would not necessarily reveal art on any of the other molecules of the inventive groups. Therefore, the searches for each invention in Groups V-XI, although classified alike, are not coextensive and would require a specific, unique search of the polynucleotide sequence of each polynucleotide claimed.

Inventions XII-XIII are directed to methods using various VEGF proteins, which differ in amino acid sequence. While each of the different proteins of the inventive groups are all considered VEGF molecules, they each have their own unique properties, and therefore, their own modes of operation (i.e. receptor binding) and their own biological effects. Furthermore, a search of one protein would not necessarily reveal art on any of the other proteins. Therefore, the searches for each method of Groups XII-XIII, although classified alike, are not coextensive and would require a specific, unique search of the amino acid sequence of each protein used in the claimed method.

Inventions (I-V) and (VI-XI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Groups I-V could be made with the polynucleotides of Groups VI-XI, but they could also be made synthetically. Furthermore, the different inventions are also directed to chemically different compounds which can be made and used without each other.

Inventions (I-V) and (XII-XIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups I-V could be used for an entirely different purpose such as for the production of the antibodies, rather than in the methods of stimulating proliferation of Groups XII-XIII.

Inventions (VI-XI) and (XII-XIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 and 808.01). In the instant case, the different inventions are not

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related because the methods of Groups XII-XIII do not require the polynucleotides of Groups (VI-XI) (i.e. not disclosed as capable of use together).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Rejoinder Practice

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to a final rejection or notice of allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the even of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

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requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidelines on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined (including election of species) even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The Examiner can normally be reached on Monday-Friday, 6AM to 2:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Christine J. Saoud". The signature is written in a cursive, flowing style.